REMARKS

Applicant respectfully requests reconsideration of this application in view of the foregoing amendments and the following remarks.

A. Introductory Remarks

Upon entry of the foregoing amendments, claims 41-67 will be pending in the application. Claims 1-40 are currently canceled. Claims 41-67 are currently added.

Support for new claims 41-67 exists throughout the specification and original claims. The following table identifies exemplary support for the new claims.

Claims	Exemplary Support
Claim 41	Original claims 1 & 19; page 3, lines 29-32; page 4, lines 14-31; page 5, lines 1-10; page 10, lines 23-26 & 32-34; page 11, lines 5-6
Claims 42-44	Original claims 1 & 20; page 16, line 14 through page 17, line 2
Claims 45, 50-51, 58-59 & 66-67	Page 21, lines 3-6
Claims 46, 52, 60 & 62	Page 10, lines 25-26 & 32-33; page 11, lines 5-6
Claims 47, 53 & 61	Original claims 1, 2 & 19; page 10, lines 25-26 & 32-34; page 11, lines 5-6
Claims 48 & 54	Original claim 24; page 3, lines 19-26
Claims 49 & 55	Original claim 6; page 6, ll. 22-24; page 17, line 28 through page 18, line 27
Claim 56	Original claim 54
Claim 57	Original claim 25; page 3, lines 26-27
Claims 63-65	Page 10, lines 1-9

B. Method Claims 41-51 Meet the Enablement Requirement of 35 U.S.C. § 112

The Office has alleged that claims 1-16, 19-22 and 34 failed to meet the "enablement" requirement because they encompass the *prevention* of several inflammatory and autoimmune diseases. The Office acknowledged the specification, however, as "being enabling for *treatment* of inflammation, hypersensitivity, autoimmune disease, chronic inflammation disease, psoriasis, dermatitis, Crohn's disease, ulcerative colitis, rheumatoid arthritis, osteoarthritis, and pain."

Pending method claims 41-51 are directed to the very subject matter that the Office acknowledged as being enabled: *treatment* of autoimmune and inflammatory diseases, including psoriasis, atopic eczema, contact dermatitis, Crohn's disease, ulcerative colitis, rheumatoid arthritis and osteoarthritis. Accordingly, the enablement rejection is inapplicable to the pending claims.

C. Claims 41-67 Are Directed to Patentable Subject Matter

The Office rejected claims 10-16 under 35 U.S.C. §§ 101 and 112, second paragraph, as allegedly being directed to "a use, without setting forth any steps." The rejection is now moot.

All of the pending claims are directed to patentable subject matter. In particular, claims 41-51 recite at least one affirmative step. Accordingly, Applicant request withdrawal of the rejection.

D. Claims 41-67 Are Patentable Over WO 98/01126 (Van Amerongen et al.)

The Office asserted that WO 98/01126 ("Van Amerongen") anticipated a number of claims under 35 U.S.C. § 102(b). The reference is inapplicable to the pending claims, however.

Van Amerongen relates to a process for manufacturing a mixture of fatty acid esters, including sterol esters isolated from sheanut. The reference suggests nothing regarding a mixture that contains the quantities of lupeol, α-amyrin and β-amyrin, and butyrospermol recited in claims 41-67. Rather, Van Amerongen states that a mixture of sterol esters may contain α-amyrin, β-amyrin, lupeol, and butyrospermol in the following quantities:

amyrin (α & β combined)	2.2-70 wt%
lupeol	0.2-35 wt%
butyrospermol	2-45 wt%

(*See, e.g.,* page 10 at lines 25-37).

By contrast, the present claims require at least 5 wt% of amyrin, lupeol and butyrospermol. *See, e.g.,* claim 41. Because the mixtures of Van Amerongen may comprise less than 5 wt% of any or all of these sterols, Van Amerongen does not anticipate the present claims.

Nothing in Van Amerongen implicates other elements of the present claims. Thus, Van Amerongen fails to teach or suggest that oral administration of the sterol ester mixture can treat inflammatory and autoimmune conditions. Instead, Van Amerongen is directed solely to reducing serum cholesterol levels. *See, e.g.*, page 1, lines 1-11, and page 2, line 27 through page 3, line 4. Van Amerongen makes no suggestion of a capsule dosage form, but instead focuses on the use of the sterol ester mixture as a fat substitute in food products. *See, e.g.*, page 11, line 15 through page 14, line 33.

Because Van Amerongen lacks any teaching or suggestion of multiple claim elements, Applicant respectfully requests withdrawal of the rejection based on that reference.

E. Claims 41-67 Are Patentable Over U.S. Patent 5,679,393 (Lauer et al.)

The Office asserted that U.S. Patent 5,679,393 ("Lauer") either anticipated or rendered obvious a number of claims. Applicants respectfully traverse the rejection, as Lauer neither teaches nor suggests the claimed invention.

Lauer relates to a process for preparing a fat fraction of vegetable material, including shea material. *See, e.g.*, abstract and column 1, line 46. According to Lauer, such fat fractions have anti-inflammatory activity and are useful in dermatological compositions. *See, e.g.,* column 5, lines 23-24 and 48-61. Yet Lauer does not teach or suggest compositions that contain the quantities of lupeol, α-amyrin and β-amyrin, and butyrospermol recited in claims 41-67.

Lauer describes mixtures of *unsaponifiable fractions* as containing from 18% to 50 % by weight of *unsaponifiable compounds*. *See* column 5, lines 40-41. These numbers are consistent with the experimental data provided. In Table VII, for example, the total content of unsaponifiable compounds in the fractions entitled "Hot-insoluble (gums)" vary between 34-46%. The nature of the compounds present in the various fractions of Lauer is discussed in more detail at column 11, lines 42-51. There it is explained that:

> (1) The *cold-insoluble fraction* contains almost exclusively triglycerides. This is consistent with the data presented in Table VIII (based on GC chromatography), where the cold-insoluble fractions A, B and C contain 82.0%, 93.6% and 97.7% triglycerides, respectively.
>
> (2) A mixture of the *hot insoluble fraction* and the *cold-soluble fraction* contains sterols, free fatty acids, aliphatic and triterpene fatty alcohols, triglycerides and very apolar constituents. It is explained (column 11, lines 50-51) that the latter correspond to the hot insoluble fraction, *i.e.*, karatines and gums. Thus, essentially all of the triterpenes are present in the cold-soluble fraction.

A more detailed description of the amounts of various compounds in the mixture of the hot insoluble fraction and the cold-soluble fraction is given in Table VIII, which shows that the combined fractions of hot insoluble and cold soluble contain from 9.8% to 12.3% "sterols + alcohols." Accordingly, the *fractions* disclosed in Laur have a maximum triterpene content that varies between 9.8% and 12.3%. Within that total triterpene content, each of amyrin, lupeol and butyrospermol may or may not even be present, as explained in Applicant's prior responses.

By contrast, the present claims require at least 5 wt%, at least 8 wt% or at least 10 wt% of amyrin, lupeol and butyrospermol, which amounts to a minimum triterpene content of 15 wt%, 24 wt% or 30 wt%. See claim 41, *inter alia*. Because the fractions of Lauer cannot contain the required amounts of amyrin, lupeol and butyrospermol, the reference does not anticipate the present claims. Additionally, because each of amyrin, lupeol and butyrospermol may or may not even be present in the fractions of Lauer, the reference

provides no motivation or suggestion to have at least 5%, at least 8% or at least 10% of each of each present in a composition.

Lauer also lacks any suggestion of other claim elements. For example, because Lauer is directed to topical formulations of "cosmetic or pharmaceutical compositions, especially dermatological compositions," the reference does not teach or suggest that *oral administration* of shea fractions is useful to treat inflammatory or autoimmune disorders. Accordingly, Lauer also lacks any teaching or suggestion of a capsule dosage form.

Because Lauer lacks any teaching or suggestion of multiple claim elements, Applicant respectfully requests withdrawal of the rejections based on that reference.

F. Claims 41-67 Are Patentable Over WO 99/63031 (Alander et al.)

The Office asserted that Alander *et al.* anticipated a number of claims. Applicant respectfully traverses the rejection, as Alander does not even suggest the claimed invention, let alone teach it, as such.

Alander relates to a process for fractionating a vegetable oil, yielding a solid fraction suitable for confectionary applications and a liquid fraction rich in unsaponifiable, biologically active components. *See* the abstract. According to Alander, the liquid fraction of shea butter "can be used as an ingredient of a cosmetical or pharmaceutical preparation, especially for providing UV-protecting and skin moisturizing properties." Page 14, 1st paragraph.

Alander does not teach compositions that contain the quantities of lupeol, α-amyrin and β-amyrin, and butyrospermol recited in claims 41-67. The shea butter fraction of Alander contains 10-25% cinnamic esters of triterpene alcohols and 5-10% fatty acid esters of triterpene alcohols (page 13, lines 21-26), *i.e.*, a shea butter fraction containing 15-35% triterpene esters. These numbers are consistent with the experimental data of Alander. In Table 3 for example, Alander describes that the F2 fraction obtained in Example 5 contains a total of 24.0% triterpene esters (16.7% + 7.3%) and that the F2 fraction obtained in Example 6 contains a total of 22.0% triterpene esters (15.4% + 6.6%). Additionally, Example 8 of Alander describes that further refinement of the fraction obtained in Example 5 gave rise to a

fraction containing 31.7% triterpene esters. A distribution of triterpene esters also is shown in Table 3. Percentages in that table, however, are not total triterpene content of the fractions, but the amount of individual triterpene cinnemates relative to the total amount of triterpene cinnemates.

At most, therefore, Alander describes a triterpene-rich fraction containing 35% triterpene cinnemates (cf. page 13, lines 21-26) that, based on the distributions shown in Table 3, contains a maximal amount of the following components:

amyrin (α & β combined)	16.1%
lupeol	3.2%
butyrospermol	5.6%

By contrast, the present claims require at least 5 wt%, at least 8 wt% or at least 10 wt% each of amyrin, lupeol and butyrospermol. *See, e.g.,* claim 41. Because the fractions of Alander lack the required amounts of amyrin, lupeol and butyrospermol, the reference does not anticipate the present claims.

Alander also lacks any teaching or suggestion of other claim elements. For example, Lauer is directed to the use of the triterpene-rich shea fraction in *topical formulations*, as a UV protection and moisturizer. Alander does not even hint *oral administration* of triterpene-rich shea fractions is useful to treat inflammatory or autoimmune disorders. Accordingly, Lauer also lacks any teaching or suggestion of a capsule dosage form.

Because Alander lacks any teaching or suggestion of multiple claim elements, Applicant respectfully requests withdrawal of the rejection based on that reference.

G. Rule 1.105 Request for Information

The examiner requested information regarding the natural range of triterpenes, sterols, karitenes, and the total amount of unsaponifiable material in shea butter. That information is presented below and can be obtained from the literature, including the following:

a) Itoh: *Oleagineux* (1974) 29(5), pp. 253-58.

b) Peers: *J. Sci. Food and Agriculture* (1977) 28, pp. 1000-09

c) Itoh: *Lipid* (1980) 15, pp. 407-11

d) Paquot: *Oleagineux* (1952) 7, pp. 397-402.

The total content of unsaponifiable material in shea butter is about 17%. The relative content of triterpenes in that unsaponifiable portion of shea butter ranges from 65% to 75%, the relative content of sterols ranges from 3% to 7%, and the relative content of karitenes ranges from 18% to 30%. On average, therefore, about 70% of the unsaponifiable portion of shea butter consists of triterpenes and 25% of the unsaponifiable portion consists of karitenes. Multiplying these numbers by 17% (the unsaponifiable portion of shea butter is only 17%), the total content of triterpenes in shea butter is about 11.9% (average) and the total content of karitenes in shea butter is about 4.25% (average). These numbers and calculations are shown in the table below.

Class of Compounds in Shea Butter	**Min. Content (% w/w)**	**Max. Content (% w/w)**	**Avg. Content (% w/w)**
Triterpenes	65 x 0.17 = **11.05**	75 x 0.17 = **12.75**	70 x 0.17 = **11.9**
Sterols	3 x 0.17 = **0.51**	7 x 0.17 = **1.19**	5 x 0.17 = **0.85**
Karitenes	18 x 0.17 = **3.06**	30 x 0.17 = **5.1**	25 x 0.17 = **4.25**

The average relative content of the triterpenes butyrospermol, amyrin (α & β combined) and lupeol are as follows:

amyrin (α & β combined)	51%
lupeol	18%
butyrospermol	21%

The examiner also requested information regarding the concentration of shea butter components obtained by conventional extraction processes. That information is provided above, in Applicant's analysis of the art cited against this application.

H. Concluding Comments

Applicant believes that this application is now in condition for allowance, and requests favorable reconsideration of it. If the Examiner believes that an interview would advance prosecution of the application, she is invited to contact the undersigned attorney by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 26 July 2005 By S. A. Bent

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768